F1 cont'd polymers, and d-alpha tocopheryl polyethylene glycol 1000 succinate wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.

REMARKS

The present invention is directed to a composition consisting essentially of a fibrate dissolved in at least one oil with a specified emulsifier that is capable of forming an emulsion upon dilution in an aqueous medium. Applicants have added new claim 19, directed to a preferred embodiment of the present invention.

The Office Action rejected claims 1, 3 and 7-12 under 35 U.S.C. §103(a) as being unpatentable over Lacy et al. (U.S. Patent No. 5,645,856).

In making this rejection, the Examiner stated, "Lacy et al. (USPN 5,645,856) teaches a carrier system for a hydrophobic drug (including fenofibrate) composition comprising (a) a digestible oil (including soybean oil, coconut oil, corn oil, palm oil, cottonseed oil, olive oil, safflower seed oil); (b) a pharmaceutically acceptable surfactant comprising a hydrophilic (including phospholipids, polyoxyethylene sorbitan fatty acid derivatives, castor oil or hydrogenated ester castor oil ethoxylates, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers and block co-polymers) and a lipophilic surfactant (including propylene glycol), see in particular col. 3, lines 38-67, cols. 5-9 and col. 11, lines 22-23, see col. 21, example 6, lines 21-31."

While Lacy et al. teach a carrier system for a hydrophobic drug comprising (a) a digestible oil and (b) a pharmaceutically acceptable surfactant comprising a hydrophilic surfactant component and a lipophilic surfactant component, Lacy et al. describe the surfactant as being capable of

"dispersing" the oil in vivo upon administration. Lacy et al. describe the surfactant as comprising a hydrophilic surfactant component, and being such that it does not substantially inhibit the lipolysis of the oil. Lacy et al., in a preferred aspect, still further describe the surfactant as comprising a hydrophilic surfactant component which substantially inhibits the in vivo lipolysis of a digestible oil and a lipophilic surfactant component capable of at least substantially reducing said inhibitory effect of said hydrophilic surfactant component (column 3, lines 38-67).

The present invention, as set forth in claim 1, provides a composition consisting essentially of a fibrate dissolved in at least one oil with one selected emulsifier. The emulsifiers used in the present invention do not exhibit or demonstrate the property of not substantially inhibiting the lipolysis of the oil. The emulsifier does not contain a hydrophilic surfactant component that substantially inhibits the in vivo lipolysis of an oil, and a lipophilic surfactant component capable of at least substantially reducing said inhibitory effect of said hydrophilic surfactant component as provided by Lacy et al. Fibrates are simply dissolved in at least one oil with one selected emulsifier; there is no requirement for a surfactant that does not substantially inhibit lipolysis. The inclusion of a surfactant that does not substantially inhibit lipolysis of an oil is an important property of Lacy's compositions (column 3, lines 38-45 and claim 1); this is NOT a property of the presently claimed invention. Thus, the present compositions would not be obvious in view of Lacy et al.

The Examiner also stated, "Note that the addition or subtraction of a pharmaceutical auxiliary or excipient, such as a surfactant (emulsifier), is within the purview of the skilled artisan and is therefore obvious, absent evidence to the contrary."

The surfactant of Lacy's compositions is not simply a pharmaceutical "auxiliary," but the basis and foundation of the described carrier for hydrophobic drugs. Thus, it would not have been obvious to one of ordinary skill in the art to employ a composition consisting essentially of a fibrate dissolved in at least one oil with one recited emulsifier.

Favorable consideration and allowance of claims 1, 3, 7-12 and 19 is respectfully requested.

If any fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 23-0785.

Respectfully submitted,

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER

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